STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

July 20, 2018

Ms. Dawn Rudolph, Administrator
St Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

Dear Ms. Rudolph:

Unannounced visits were made to St Vincent's Medical Center concluding on May 8, 2018 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

A telephone conference has been scheduled for **August 10, 2018 at 9:00 AM** to discuss the violations with an asterisk (*) . Should you wish to retain legal representation, your attorney may accompany you to this meeting. Please call me directly to participate in this meeting at (860) 509-7436.

You may wish to dispute the violation(s) and you may be provided with the opportunity to be heard. If the violation(s) is/are not responded to by **August 3, 2018** or if a request for a meeting is not made by the stipulated date, the violation(s) shall be deemed admitted.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice. The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

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Affirmative Action/Equal Opportunity Employer

DATES OF VISIT: December 5, 6, 2017 and May 7 and 8, 2018

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

If there are any questions, please di not hesitate to contact this office at (860) 509-7400.

Respectfully,

/ s /

Cheryl A. Davis, R.N., B.S.N.
Supervising Nurse Consultant
Facility Licensing and Investigations Section

CAD/PB:jf

Complaints #22358, #21340 and #23356

DATES OF VISIT: December 5, 6, 2017 and May 7 and 8, 2018

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical staff (4)(A) and/or (i) General (6).

1. **Based on a review of clinical records, interviews and policy review, for one (1) of twenty (20) records reviewed for emergency room care and services (Patient #1), the hospital failed to ensure that the on-call hand surgeon evaluated the patient when s/he presented to the ED with a left traumatic 3rd digit amputation through the middle phalanx and concomitant injuries to the 2nd and 4th digits. The finding includes the following:
    a. Patient #1, a 72 year old presented to the ED on 4/22/18 at 7:32 PM via EMS after sustaining an injury while using a table saw. The patient had a past medical history of diabetes, coronary artery disease, hypertension and myocardial infarction. Review of MD #1's assessment dated 4/22/18 at 7:28 PM indicated that the patient was working with a table saw when a piece of wood threw the blade back and took the distal phalanx of his/her third finger and tips of the 2nd and 4th fingers. The lacerations were jagged in nature and bone was exposed on digits 2-4. Review of the radiological report dated 4/22/18 at 8:12 PM identified that there were amputation deformities of the distal second and third digits with absence of the distal phalanx of the third digit as well as the tuft of the distal second phalanx. There is probable involvement of the distal tip of the middle third phalanx. The distal interphalangeal joint (DIP) of the third digit is disrupted.

       Review of MD #1's progress note at 8:17 PM reflected that an emergent consult to the on-call hand surgeon, MD #2, was made, the case was described and MD #2 advised MD #1 to call hospital #2 for transfer for consideration of re-implantation as MD #2 does not perform re-implants. The note further reflected that MD #1 called hospital #2 and spoke with MD #3 about the case. MD #2 and MD #3 discussed the case and per MD #2, MD #3 would evaluate the patient. The patient was subsequently transferred to hospital #2 at 9:44 PM for evaluation of the traumatic hand injury.

       Review of the clinical record from hospital #2 dated 4/22/18 identified that the patient was transferred from hospital #1 after a table saw injury with amputation of the left 3rd finger and damage to the 2nd and 4th. The ED physician evaluated the patient at 10:37 PM and requested a plastic surgery consult. Consultation identified that the patient was evaluated and given the mechanism of injury, zone of injury, and patient's significant comorbidities, replantation versus revision amputation were explained to the patient ultimately pursuing revision amputation. The patient subsequently had the wound closed in the ED and no re implantation based on the risks and benefits reviewed. The patient was discharged home on 4/23/18 at approximately 3:10 AM.

       Interview with MD #1 on 5/7/18 at 1:30 PM stated his main goals were to get a plan to address the patient's fingers, pain control and obtain baseline bloodwork. Upon the patient's arrival to the ED, he called the on-call hand surgeon MD #2, who indicated that the patient should be transferred since she does not do re-implantations. MD #1 stated that when he spoke with the potential receiving physician (MD #3), he stated MD #2

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should see and evaluate the patient prior to transfer and this could be a case of EMTALA. After speaking to MD #3, MD #1 called MD #2 again who felt that coming in to evaluate the patient would delay the process and felt this was not an EMTALA as the patient was being transferred to a higher level of care. The patient was subsequently transferred to acute care hospital #2 on 4/22/18 at 9:44 PM.

Interview with MD #2 on 5/8/18 at 8:30 AM verified that she was called on 4/22/18 about a patient who had a distal phalanx amputation. MD #2 indicated she felt that the patient should be evaluated for microsurgery and this was not performed at the facility. MD #2 stated she reviewed a picture of the patient's hand sent to her and that she did not come into the ED to evaluate patient as this would delay potential treatment. MD #2 further stated that the receiving hospital indicated they would not refuse the patient however did request that she evaluate the patient and review options, risks and benefits. MD #2 indicated that she responded to the call, however, did not go to the ED to evaluate the patient as she felt that would delay the care.

Review of the clinical record lacked documentation that identified Patient #1 was evaluated by MD #2, the on-call hand surgeon, despite MD #1's and the receiving hospitals request to do so.

Review of the EMTALA policy indicated that the on-call physician must come to the ED when requested by the ED physician, another physician, a nurse or any hospital worker making the request on behalf of the physician or nurse. If requested, the on-call physician must come to the ED to see a patient that is being transferred to another institution before the transfer and must communicate with the receiving physician.

Review of the facility Rules and Regulations indicated that Consultations shall show evidence of the consultations review of the patient's record, pertinent findings on examinations of the patient and the consultant's opinion and recommendations.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (4) (A) and/or (e) Nursing Services (1) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

2. Based on observations, facility documentation and interviews the hospital failed to ensure infection control practices were maintained. The findings include:
    b. During tour of the operating room (O.R.) suite on 11/28/17 it was identified that two staff personnel in O.R room 6 had failed to cover their entire head allowing hair to be exposed at the back and sides during a procedure. Review of the Surgical Attire policy identified hair shall be covered with a lint free-free surgical cap/hood.
    c. During tour of the O.R. suite on 11/28/17 it was identified two O.R. tables which had recently been cleaned revealed multiple wet areas when the table linen and padding were moved. In addition suture material with tissue attached was identified on the floor in an OR room. In an interview on 11/28/17 at 10:40AM the O.R Attendant identified

the steps to clean an OR room in between cases includes mopping the floor for any visible soiled areas and when cleaning the table the surface must be exposed for 10 minutes to allow for drying. Review of the OR cleaning policy identified that the cleaning solution needs to dry for at least 10 minutes.

c. During tour of the O.R suite on 11/28/17 it was identified in O.R room 7 a 3 liter intravenous (IV) bag of saline solution was located in the fluid/blanket warmer without an outer wrapper. In an interview on 11/28/17 at 1:10PM, the Director of Surgical Services identified the IV solution should not be kept in the fluid/blanket warmer and that there are other methods to warm the solution. The Director of Surgical Services also identified the outer wrapper serves as a protective cover and if removed the IV solution should be discarded if not used. Review of the Fluid/Blanket warming policy identified IV solutions should only be warmed using technology designed for this purpose.

d. During tour of the telemetry unit (7 south) on 11/28/17 three glucometers were identified in the staff break room. One glucometer was located on the table near to personal staff food items and containers and was identified to have a blue colored stain across the front of the device. In an interview on 11/28/17 at 10:00AM, Nurse Manager #12 identified that the glucometers should be cleaned after each use. In addition, Nurse Manager #12 identified that the unit has been temporarily located to 7 South for renovation purposes and that space has been limited to accommodate supplies and equipment.

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3. **Based on clinical record review, facility documentation, interviews, and manufacturer instructions, for one of three sampled patients (Patient #14) reviewed for surgical procedures, the facility failed to ensure that equipment identified as being damaged was removed from circulation and not utilized during a surgical procedure. The finding includes:

   d. Patient #14 was admitted to the ambulatory surgical unit on 10/4/17 for a transurethral resection of the prostate (TURP). Patient #14 had a medical history that included bladder stones, hypertension, urolithiasis and osteoarthritis.
   Review of the Adverse Event report dated 10/4/17 identified during the TURP procedure MD#16 indicated the continuous flow pump was not functioning correctly. After the operating room (OR) staff corrected the fault the pump was able to function and the procedure continued. The report further identified after the procedure, P#14 complained of epigastric pain while in the recovery room and was subsequently diagnosed with perforation of the bladder. P#14 underwent repair of the bladder perforation on 10/4/17 and was discharged home on 10/8/17. Facility investigation identified the continuous flow pump was damaged prior to use and that tape was placed over the damaged area. No indicators were visible to identify who applied the tape.

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In an interview on 12/5/17 at 9:25 AM, the Surgical Clinical Nurse Educator (RN #15) identified she relieved the OR staff for a break after P#14 had received a spinal anesthesia and was positioned for the procedure. RN #15 identified she set up the continuous flow pump with another nurse and as the surgeon proceeded with the procedure he identified that there was a problem with the functioning of the pump. RN #15 identified the continuous flow pump's action is to allow fluid into the bladder and withdraw fluid as the prostate tissue is resected. RN #15 further identified the pump had tape attached to the front plate where tubing is threaded through but allowed the pump to be used since it appeared to be functioning after she trouble shooted the equipment. RN #15 identified that the pump should have been taken out of service and sent for repair because of the visible damage and attached tape.

In an interview on 12/6/17 at 11:40 AM, the urologist MD #16 identified he uses the continuous flow pump frequently and is very familiar with it. MD#16 identified prior to the TURP procedure he asked the OR staff (travel nurse) if they were familiar with the set-up of the pump who confirmed that they were. MD#16 stated as he was doing the procedure air was being pushed into the bladder and the fluid irrigation was backing up into the inflow irrigation tube. MD#16 believed that the tubing was incorrectly connected to the pump and once this was corrected, he was able to continue with the procedure and able to visualize that the bladder was intact. MD#16 also identified that P#14 had bladder diverticula and with a recent history of bladder stone removal the additional pressure in the bladder during the procedure may have been cumulative factors for the bladder perforation.

Review of the continuous flow pump instruction manual identified in part that it is extremely important that the tubing be properly connected in the correct direction through the pump head.

<u>The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1) and/or (i) General (6).</u>

4. Based on clinical record review, facility documentation, interviews, and policy review, for one of three sampled patients (Patient #9) reviewed for falls, the facility failed to ensure that the fall protocol was implemented in accordance with facility policy. The finding includes:
    e. Patient (PT) #9 was admitted on 12/27/16 with a diagnosis of shortness of breath and pleural effusions. Patient #9's medical history included multiple myeloma, hypertension, depression and anxiety.

    Review of the clinical record dated 12/27/16 identified that the patient had a Hendrich score of six (6) indicating that the patient was at risk for falls. Interventions to the plan of care included, wheels locked, bed in low position, call device within reach, and upper half length side rails in the upward position for bed mobility.

    Clinical record review identified on 12/31/16 at 8:00AM, the patient's Hendrich score was 5, patient considered at risk to fall. Attempts to extubate PT#9 that morning were unsuccessful therefore Propofol sedation continued. Review of facility documentation

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identified that on 12/31/18 at 2:30PM, the RN left PT#9's room and shortly thereafter the patient was found on the floor laying on his/her right side. The Trauma team responded and assessment identified ecchymosis to forehead; CT scan of brain, spine, chest and abdomen reported negative findings and no fracture. A high risk fall management intervention plan of care was initiated post fall which included placement of a tab and bed alarm. Documentation further identified on 1/1/17 PT#9 was noted to have right side orbital hematoma, unequal pupils with right lateral eye deviation. A CT scan of the brain reported small right sided intraventricular hemorrhage (IVH), subsequent neurology consult reported no surgical intervention required. On 1/2/17 the patient was successfully extubated and complained of right elbow pain, subsequent x-ray and orthopedic consult reported minimally displaced fracture of the right humerus; no surgical intervention required.

In an interview on 12/5/17 at 1:00PM, Nurse Manager (NM) #5 (the Clinical Nurse Leader of ICU) identified the fall protocol is initiated for Hendrich scale score of 5 or more with interventions such as raised side rails and bed alarm. NM #5 further identified that the fall protocol was not initiated on the admitting fall assessment which would include placing a bed alarm.

Review of the Fall Prevention policy directed that all patients, 18 years and older will be assessed for risk to fall using the Hendrich fall risk model assessment criteria, upon admission and at least once during an 8 hour shift. A score of 5 or greater indicates that the patient is a high fall risk and will be placed on the Ruby slipper Fall Prevention Program. Interventions include but are not limited to the use of a removable bed/chair alarm.

<u>The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1)</u>

5. Based on clinical record review, interview and policy review, for 3 of 20 records reviewed for pain (Patients #1, 14 and 16), the facility failed to ensure the patient's pain was reassessed to determine the efficacy of the intervention. The findings include the following:
    a. Patient #1 presented to the ED on 4/22/18 at 7:32 PM after amputating the third distal phalange and partial amputation of the 2nd distal phalange on the left hand. The record indicated that the patient rated pain level as a 10 on a scale of 0-10 (with 10 being the worst pain possible). The patient received 4 milligrams of Morphine intravenously at 7:49 PM, 8:16 PM and 8:40 PM. The record failed to reflect a reassessment of the patient's level of pain after the administration of medication. The patient rated pain as a 10 at 9:17 PM at which time Dilaudid 1 mg IV was administered, however, the record failed to reflect a reassessment of the patient's pain level.
    b. Patient #14 presented to the ED on 4/18/18 at 11:52 AM with a finger injury. The patient was seen in triage at 11:56 AM and rated pain as a 10 at 12:00 PM with Morphine 1 mg IV administered at 12:35 PM. The record failed to reflect that the patient's level of pain was reassessed until 3:45 PM.

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c. Patient #16 presented to the ED on 4/17/18 at 8:49 AM with complaints of right hand swelling and cold to touch. The patient rated pain as a 9 at 8:50 AM. The record reflected that the patient did not receive pain medication until 10:13 AM (Fentanyl 50 mcg intravenously). At 10:41 AM, the patient reported a pain level of 6 with Fentanyl 100 mcg IV administered at 11:13 AM. The record failed to reassess the patient's pain until 12:51 PM when the patient indicated his/her pain level was an 8. At 3:04 PM, the patient received Fentanyl 100 mcg IV however the record failed to reflect a reassessment of the patient's pain level until 5:49 PM at which time it was a 10.

Interview with the Nurse Manager on 5/8/18 at 2:00 PM stated the patient's level of pain should have been reassessed in accordance with facility policy. Review of the policy indicated that the patient's pain level should be assessed every eight hours and 30-60 minutes post a pharmacological intervention. Thirty minutes for parenteral medication and 60 minutes for oral medication.